

**REMARKS****35 U.S.C. §102**

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

**Claims 1-10**

The rejection of claims 1-10 is respectfully traversed.

Claim 1 claims "[a]n apparatus for creating an opening in a tissue vessel and introducing an object into the vessel through the opening, the apparatus comprising: a hollow member; a piercing element movable relative to said hollow member to remove a tissue plug from the vessel and thereby create an opening therein; and an introducer located substantially around at least part of said hollow member, wherein said piercing element and said hollow member are movable relative to said introducer to allow introduction of the object into the opening in the vessel through said introducer."

In contrast, Mayenberger does not expressly or inherently describe a piercing element and a hollow member movable relative to an introducer to allow introduction of a workpiece object into an opening in the vessel through that introducer. First, at no time in the operation of the device of Mayenberger is there space within the tubular member 1 to move a workpiece object through it. "[T]he cutting member 28 is held undetachably in the sleeve 18." (col. 8, lines 14-15). That is, the cutting member 28 remains in the sleeve 18 during operation of the device. The sleeve 18 in turn is positioned at the distal end of the tubular shaft 1, and has a lumen adjacent to and with the same internal diameter as the lumen of the tubular shaft 1.

(e.g., Figures 1-3, 5). As a result, the cutting member 28 blocks the lumen of the tubular shaft 1 during operation of the device, such that the cutting member 28 is not movable relative to the tubular shaft 1 to allow introduction of a workpiece object into the opening in the vessel through that tubular shaft 1.

Second, Mayenberger discloses nothing about a workpiece object, much less motion of the piercing element and hollow member relative to the introducer to allow introduction of that workpiece object into an opening in the vessel. The only object in Mayenberger that is introduced into the vessel is the cutting member 28. (e.g., Figures 1-2). However, the Office Action analogizes that to the claimed piercing element of claim 1, which is separate and different from the workpiece object manipulated by the structure of claim 1.

Third, during operation of the device, the sleeve 18 is locked in place relative to the tubular shaft 1. (e.g., col. 7, lines 22-27 ("During this entire operating procedure...locking of the sleeve 18 in relation to the shaft 1...is maintained"); col. 5, lines 51-53 ("the sleeve 18 ends in a sharp, annular cutting edge 23")). Mayenberger fails to disclose any other hollow members movable relative to the tubular shaft 1 during operation of the device. Thus, Mayenberger does not disclose the claimed "hollow member movable relative to an introducer." (emphasis added).

#### Claims 11-15

The rejection of claims 11-15 is respectfully traversed.

Claim 11 claims "[a] system for performing anastomosis to a tissue vessel; the apparatus comprising: a cutter; an element movable relative to said cutter to remove a tissue plug from the vessel and thereby create an opening therein; an anastomosis device; and an introducer having an axis substantially along which said anastomosis device is introduceable

into the opening, wherein said element and said cutter are movable away from said axis to allow motion of said anastomosis device substantially along said axis.” (emphasis added).

In contrast, Mayenberger does not expressly or inherently describe the claimed anastomosis device. The device of Mayenberger is simply a surgical punch. Nowhere in the Mayenberger reference is the claimed anastomosis device disclosed. Indeed, Mayenberger fails to disclose connecting tissue vessels at all, much less an anastomosis device or any other apparatus or method for making such a connection.

Further, Mayenberger does not disclose an “introducer having an axis...wherein said element and said cutter are movable away from said axis.” The Office Action analogizes the tubular shaft 1 of Mayenberger to the claimed introducer. Further, the Office Action implies that the claimed cutter is analogous to the cutting edge 23 of Mayenberger, and that the claimed element is analogous to the piercing element 28. The cutting edge 23 remains stationary relative to the tubular shaft 1 during actuation of the surgical punch. (e.g., col. 7, lines 22-27 (“During this entire operating procedure...locking of the sleeve 18 in relation to the shaft 1...is maintained”); col. 5, lines 51-53 (“the sleeve 18 ends in a sharp, annular cutting edge 23”)). Further, the piercing element 28 only moves linearly along the tubular shaft 1 – that is, along the axis of the tubular shaft 1. (e.g., col. 7, lines 13-16; Figures 1-2, 5-6) Indeed, the inner diameter of the tubular shaft 1 and the outer diameter of the piercing element 28 are substantially the same, such that the piercing element 28 cannot be moved away from the axis of the tubular shaft 1. (e.g., Figure 6). Thus, Mayenberger does not disclose an “introducer having an axis...wherein said element and said cutter are movable away from said axis.”

Thus, Mayenberger does not expressly or inherently describe each and every element of claim 11, and Applicants believe claim 11 is in condition for allowance. Claims 12-15 depend from claim 11, and are thus believed to be in condition for allowance as well under

MPEP 608.01(n)(III).

Claims 16-32

The rejection of claims 16-32 is respectfully traversed.

Claim 16 claims “[a] tissue cutting system for creating an opening in a tissue vessel, comprising: a cutter; a piercing element movable relative to said cutter to remove a tissue plug from the vessel, said piercing element defining a tissue receiving space proximal to its distal end; and a member configured to receive said piercing element, said member having an aperture defined in a side thereof through which said piercing element is at least partially removable.” (emphasis added).

The Office Action implies that the tubular shaft 1 of Mayenberger is analogous to the claimed member of claim 16. However, the only openings or apertures in the tubular shaft 1 are at the proximal and distal ends of that tubular shaft 1. (e.g., Figures 1-3, 5-6). The tubular shaft 1 does not have an “aperture defined in a side thereof.” Further, Mayenberger fails to disclose any other structure that is “configured to receive said piercing element” that has an “aperture defined in a side thereof.”

Thus, Mayenberger does not expressly or inherently describe each and every element of claim 16, and Applicants believe claim 16 is in condition for allowance. Claims 17-32 depend from claim 16, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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